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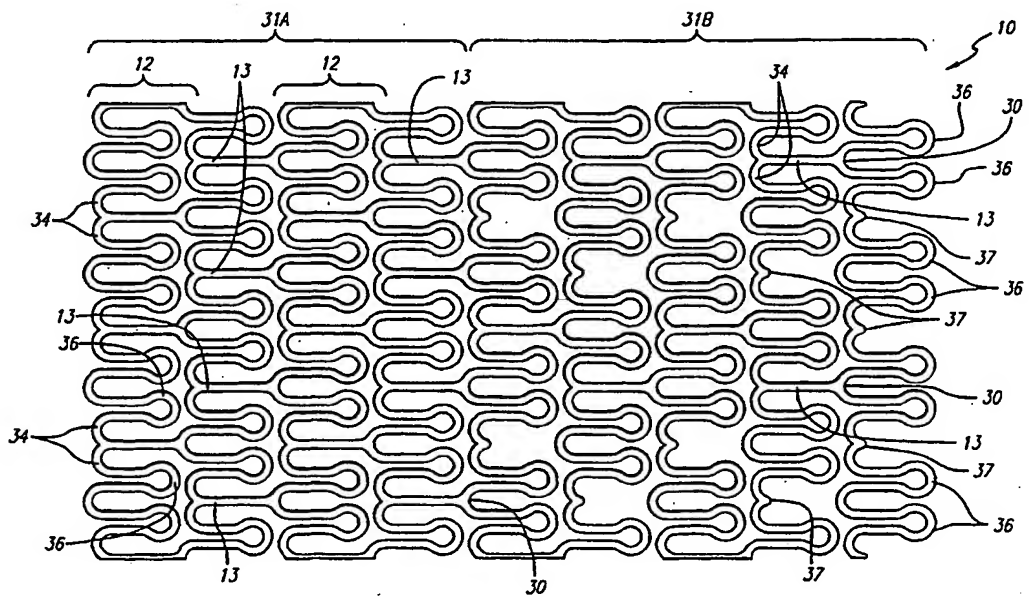

(57) Abstract

An expandable stent for implantation in a body lumen, such as an artery, is disclosed. The stent consists of a plurality of radially expandable cylindrical elements generally aligned on a common longitudinal stent axis and interconnected by one or more interconnecting members placed so that the stent is flexible in the longitudinal direction. At least one end of the opposite ends of the stent has fewer interconnecting members than a center section of the stent to provide localized flexibility to a selected region of the stent.

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STENT WITH CUSTOMIZED FLEXIBILITY

BACKGROUND OF THE INVENTION

This is a continuation-in-part application of co-pending parent application Serial No. 09/008,366, filed January 16, 1998, the entire contents of which hereby are incorporated by reference.

This invention relates to expandable endoprosthesis devices, generally known as stents, which are designed for implantation in a patient's body lumen, such as a blood vessel to maintain the patency thereof. These devices are particularly useful in the treatment and repair of blood vessels after a stenosis has been compressed by percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal angioplasty (PTA), or has been removed by atherectomy or other means.

Stents generally are cylindrically-shaped devices which function to hold open and sometimes to expand a segment of a blood vessel or other lumen, such as a coronary artery. Stents are particularly suitable for use to support the lumen or to hold back a dissected arterial lining which can occlude the fluid passageway therethrough.

A variety of devices are known in the art for use as stents and have included balloon expandable stents; coiled wires in a variety of patterns that are expanded after being placed intraluminally on a balloon catheter; helically-wound coiled springs manufactured from an expandable, heat sensitive metal; and self-expanding stents inserted in a compressed state and shaped in a zigzag pattern. One of the difficulties encountered using prior art stents involved maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery and to accommodate the often tortuous path of the body lumen.

Another problem area has been the limited range of expandability. Certain prior art stents expand only to a limited degree due to the uneven stresses created upon the stents during radial expansion. This necessitates providing stents with a variety of diameters, thus increasing the cost of manufacture. Additionally, having a stent with a wider range of expandability allows the physician to re-dilate the stent if the original vessel size was miscalculated.

Another problem with the prior art stents has been contraction of the stent along its longitudinal axis upon radial expansion of the stent. This can cause placement problems within the artery during expansion.

Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition, and then deflating the balloon and removing the catheter.

What has been needed is a stent which has an enhanced degree of flexibility so that it can be readily advanced through tortuous passageways and radially expanded over a wider range of diameters with minimal longitudinal contraction to accommodate a greater range of vessel diameters, all with minimal longitudinal contraction. The expanded stent of course also must have adequate structural strength (hoop strength) to hold open the body lumen in which it is expanded. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to stents of enhanced longitudinal flexibility and configuration which permit the stents to expand radially to accommodate a

greater number of different diameter vessels, both large and small, than heretofore was possible. The stents also have greater flexibility along the longitudinal axis to facilitate delivery through tortuous body lumens, but remain highly stable when expanded radially, to maintain the patency of a body lumen such as an artery or other vessel when implanted therein. The unique patterns of the stents of the instant invention permit both greater longitudinal flexibility and enhanced radial expandability and stability compared to prior art stents.

Each of the different embodiments of stents of the present invention includes a plurality of adjacent cylindrical elements which are generally expandable in the radial direction and arranged in alignment along a longitudinal stent axis. The cylindrical elements are formed in a variety of serpentine wave patterns transverse to the longitudinal axis and contain a plurality of alternating peaks and valleys. At least one interconnecting member extends between adjacent cylindrical elements and connects the cylindrical elements to one another. These interconnecting members insure minimal longitudinal contraction during radial expansion of the stent in the body vessel. The serpentine patterns have varying degrees of curvature in the regions of the peaks and valleys and are adapted so that radial expansion of the cylindrical elements is generally uniform around the circumference of the cylindrical elements when the stent transitions from the contracted conditions to the expanded conditions.

The resulting stent structures are a series of radially expandable cylindrical elements that are spaced longitudinally closely enough so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so closely as to compromise the longitudinal flexibility of the stent both when the stent is being negotiated through the body lumens in the unexpanded state and when the stent is expanded into position. The serpentine patterns allow for an even expansion around the circumference by accounting for the relative differences in stress created by the radial expansion of the cylindrical elements.

Each of the individual cylindrical elements may rotate slightly relative to their adjacent cylindrical elements without significant deformation, cumulatively providing stents which are flexible along the length thereof and about the longitudinal axis, but which still are very stable in the radial direction in order to resist collapse after expansion.

Each of the stents of the present invention can be readily delivered to the desired lumenal location by mounting onto an expandable member, such as a balloon, of a delivery catheter and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stents to the expandable member of the catheter for delivery to the desired location are available. It presently is preferred to compress or crimp the stent onto the unexpanded balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, using bioabsorbable temporary adhesives, or adding a retractable sheath to cover the stent during delivery through a body lumen.

The presently preferred structures for the expandable cylindrical elements which form the stents of the present invention includes a circumferential serpentine pattern containing a plurality of alternating peaks and valleys. The degrees of curvature along adjacent peaks and valleys are designed to compensate for the stresses created during expansion of the stent so that expansion of each of the peaks and valleys is uniform relative to one another. This novel structure permits the stents to radially expand from smaller first diameters to any number of larger second diameters, because stress is distributed more uniformly along the cylindrical elements. This uniformity in stress distribution reduces the tendency towards stress fractures in one particular region and allows high expansion rates.

The different stent embodiments also allow the stents to expand to various diameters from small to large to accommodate different-sized body lumens, without loss of radial strength and limited contraction of longitudinal length. The open

reticulated structure of the stents results in a low mass device. It also enables the perfusion of blood over a large portion of the arterial wall, which can improve the healing and repair of a damaged arterial lining.

In one presently preferred embodiment, the ability of the stent to treat larger diameter vessels results from increasing the number of units of the repeating pattern of peaks and valleys so that the starting compressed diameter is larger than in prior art devices. When expanded, the stent of this embodiment has sufficient coverage of the lumenal wall and maintains its structural integrity due to forces imposed by the lumenal wall and therefore resists collapse.

The serpentine patterns of the cylindrical elements can have different degrees of curvature in adjacent peaks and valleys in order to compensate for the expansive properties of the peaks and valleys. Additionally, the degree of curvature along the peaks can be set to be different in immediately adjacent areas in order to compensate for the expansive properties of the valleys adjacent to it. The more even radial expansion of this design results in stents which can be expanded to accommodate larger diameters with minimal out-of-plane twisting, because the high stresses are not concentrated in any one particular region of the pattern, but are more evenly distributed among the peaks and valleys, allowing the peaks and valleys to expand uniformly. Reducing the amount of out-of-plane twisting also minimizes the potential for thrombus formation.

The serpentine pattern of the individual cylindrical elements can be in phase with each other serpentine pattern in order to reduce contraction of the stents along the length of the stent upon expansion. The cylindrical elements of the stents are plastically deformed when expanded (except with nickel-titanium (NiTi) alloys) so that the stents will remain in the expanded condition and, therefore, the cylindrical elements must be sufficiently rigid when expanded to prevent the collapse thereof in use.

With stents formed from super-elastic NiTi alloys, the expansion occurs when the stress of compression is removed. This allows the phase transformation from martensite back to austenite to occur, and as a result the stent expands.

After the stents are expanded, some of the peaks and/or valleys may, but do not necessarily, tip outwardly and embed in the vessel wall. Thus, after expansion, the stents might not have a smooth outer wall surface. Rather, it might have small projections which embed in the vessel wall and aid in retaining the stents in place in the vessel. The tips projecting outwardly and strut twisting are due primarily to the struts having a high aspect ratio. In one preferred embodiment, the strut is about 0.0889 mm (0.0035 in.) wide and about 0.0559 mm (0.0022 in.) thick, providing an aspect ratio of 1.6. An aspect ratio of 1.0 will produce less tipping and twisting.

The interconnecting members which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical members. The interconnecting members may be formed in a unitary structure with the expandable cylindrical elements formed from the same intermediate product, such as a tubular element, or the interconnecting members may be formed independently and mechanically secured between the expandable cylindrical elements.

Preferably, the number and location of the interconnecting members can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stents, the more easily and the more safely the stents can be delivered to the implantation site, especially when the implantation site is on a curved section of a body lumen, such as a coronary artery or a peripheral blood

vessel, and especially when the body lumen is a saphenous vein or another larger vessel.

Following from the foregoing proposition is that, in general, the more interconnecting members there are between adjacent cylindrical elements of the stent, the less longitudinally flexible is the stent. More interconnecting members reduces flexibility, but also increases the coverage of the vessel wall, which helps prevent tissue prolapse between the stent struts. Accordingly, it is possible to customize the number of connections to obtain flexibility when flexibility is most needed and coverage when coverage is most needed.

In a preferred embodiment, the present invention is directed to a longitudinally flexible stent for implanting in a body lumen and expandable from a contracted condition to an expanded condition, comprising: a plurality of adjacent cylindrical elements each having a circumference extending around a longitudinal stent axis, the cylindrical elements being arranged in cylindrical alignment along the longitudinal stent axis to form a generally tubular member; the generally tubular member having a first end section, a second end section, and a center section therebetween; and wherein the adjacent cylindrical elements in the center section are connected by n number of interconnecting members and the adjacent cylindrical elements in at least one of the first and the second end sections are connected by n-k number of interconnecting members, so that the first and second sections are relatively more flexible than the center section; wherein k is a number selected from the group consisting of 1, 2, 3, 4, or 5; and wherein $n > k$.

In this preferred embodiment construction, the first and second end sections are connected by a number of interconnecting members that is always lower than the number of interconnecting members connecting the center section of cylindrical elements in the stent. Accordingly, the present invention design is flexible in at least one end and optionally at both ends while being stiffer in the middle. In other words, in one embodiment, one end is flexible while the middle and opposite end

are relatively more rigid; in another embodiment, both ends are flexible while the middle is relatively more rigid.

This type of stent would work well for lesions located in a bend in a vessel. The stiffest portion could be located over the heaviest plaque mass. This region would have minimal separation or splay between the cylindrical elements and would therefore minimize tissue prolapse. On the other hand, the flexible ends of the stent would conform to the vessel and minimize the length of artery which is forced to be more straight by an otherwise rigid stent. The more flexible end sections also would be positioned closer to the normal portion of the artery where splay would be a less important factor. This assumes the stent has a length that is sufficient to cover the lesion and extends from a normal portion of the vessel to another normal portion of the vessel.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side elevational view, partially in section, depicting the stent embodying features of the present invention mounted on a delivery catheter and disposed within a vessel.

FIG. 2 is a side elevational view, partially in section, similar to that shown in FIG. 1, wherein the stent is expanded within a vessel, pressing the lining against the vessel wall.

FIG. 3 is a side elevational view, partially in section, showing the expanded stent within the vessel after withdrawal of the delivery catheter.

FIG. 4 is a plan view of a flattened section of one embodiment of the present invention stent which illustrates the serpentine pattern and the varying number of interconnecting members of the stent so that one end is more flexible than the other.

FIG. 5 is an enlarged partial view of the stent of FIG. 4 depicting the serpentine pattern along the peaks and valleys that form the cylindrical elements of the stent.

FIG. 6 is a perspective view of the stent of FIG. 4 in the expanded configuration.

FIG. 7 is a plan view of a flattened section of another embodiment of the present invention stent illustrating the serpentine pattern and varying the number of interconnecting members to obtain flexible end sections and a relatively rigid middle section.

FIG. 8 is a plan view of a flattened section of another embodiment of the present invention stent wherein the number of interconnecting members is varied to obtain flexible end sections.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With respect to prior art stent designs, such as the MultiLink Stent™ manufactured by Advanced Cardiovascular Systems, Inc., Santa Clara, California, a plurality of cylindrical rings are connected by three connecting members between adjacent cylindrical rings. Each of the cylindrical rings is formed of a repeating pattern of U-, Y-, and W-shaped members, typically having three repeating patterns forming each cylindrical ring. A more detailed discussion of the configuration of

the MultiLink Stent™ can be found in U.S. Patent No. 5,569,295 (Lam) and U.S. Patent No. 5,514,154 (Lau et al.).

In order to provide a highly flexible stent adapted for insertion in larger vessels, and having the ability to provide better coverage of the lumenal wall without sacrificing radial strength or flexibility, the stent of the present invention optionally adds at least one more repeating pattern of U-, Y-, and W-shaped members to each cylindrical ring. Further, two connecting members, spaced 180 degrees apart between adjacent cylindrical rings, provide for increased flexibility over the prior art stents, which is essential for delivering the present invention stent through tortuous anatomy and implanting it in a curved section of vessel.

FIG. 1 illustrates a first embodiment of a stent 10 incorporating features of the present invention which is mounted onto a delivery catheter 11. The stent generally comprises a plurality of radially expandable cylindrical elements 12 disposed generally coaxially and interconnected by interconnecting members 13 disposed between adjacent cylindrical elements 12. The delivery catheter 11 has an expandable portion or balloon 14 for expanding the stent 10 within an artery 15 or other vessel. The artery 15, as shown in FIG. 1, has a dissected or detached lining 16 which has occluded a portion of the arterial passageway.

The delivery catheter 11 onto which the stent 10 is mounted essentially is the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and, ionomers such as that manufactured under the tradename SURLYN by the Polymer Products Division of the E.I. duPont de Nemours Company. Other polymers also may be used.

In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed or crimped onto the balloon 14. A retractable protective delivery sleeve 20 may be provided to ensure that the stent 10 stays in place on the balloon 14 of the delivery catheter 11

and to prevent abrasion of the body lumen from the open surface of the stent 10 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the balloon 14. Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g., tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

In a preferred embodiment, delivery of the stent 10 is accomplished in the following manner. The stent 10 first is mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The stent 10 may be crimped down onto the balloon 14 to obtain a low profile. The catheter-stent assembly can be introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 is disposed through the damaged arterial section with the detached or dissected lining 16. The catheter-stent assembly then is advanced over the guide wire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter 11 is inflated or expanded, thus expanding the stent 10 against the inside of the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 preferably is expanded slightly by the expansion of the stent 10 to seat or otherwise embed the stent 10 to prevent movement. Indeed, in some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

While FIGS. 1-3 depict a vessel having a detached lining 16, the stent 10 can be used for purposes other than repairing the lining. Those other purposes include, for example, supporting the vessel, reducing the likelihood of restenosis, or assisting in the attachment of a vascular graft (not shown) when repairing an aortic abdominal aneurysm.

In general, the stent 10 serves to hold open the artery 15 after catheter 11 is withdrawn, as illustrated in FIG. 3. Due to the formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in a transverse cross-section so that when the stent 10 is expanded, the cylindrical elements 12 are pressed into the wall of the artery 15 and, as a result, do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of the stent 10 that are pressed into the wall of the artery 15 eventually will be covered with endothelial cell growth which growth further minimizes blood flow turbulence. The serpentine pattern of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Further, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

In one preferred embodiment of the stent 10, as depicted in FIGS. 4 and 5, the stresses involved during expansion from a low profile to an expanded profile are much more evenly distributed among the various peaks and valleys of the stent 10. As seen in FIG. 4, a portion of a cylindrical element 12 of the stent 10 embodies the serpentine pattern having a plurality of peaks and valleys that aid in the even distribution of expansion forces. In this first embodiment, the interconnecting members 13 serve to connect adjacent peaks and valleys of each adjacent cylindrical element 12 as described above. The various peaks and valleys generally have U, Y, and W shapes, in a repeating pattern, to form cylindrical element 12.

During expansion, the double-curved portions (W) 34 located in the region of the valley where the interconnecting members 13 are connected have the most mass and, accordingly, are the stiffest structure during deformation. In contrast, the peak portions (U) 36 are the least stiff, and the valley portions (Y) 30 have an

intermediate stiffness. In this FIG. 4 exemplary embodiment, there are four repeating patterns of peaks and valleys in each cylindrical element 12.

A preferred embodiment of a stent 10 can be viewed in FIG. 4 as having two sections; namely, first and second end sections 31A and 31B, respectively. As is shown, the first end section 31A has interconnecting members 13 in each double-curved portion (W) 34, thereby providing maximum support at that end of the stent. The first end section 31A optionally may contain a center section in an abstract sense, but since the theoretical center section has the same number of interconnecting members and the same cylindrical element design as the first end section 31A, it has not been divided and identified separately for the purposes of this description. In the alternative, one also may think of the embodiment shown in FIG. 4 as having the center section completely omitted.

In order to improve flexibility and uniform expansion at the second end section 31B, every second interconnecting member 13 is removed from certain of the cylindrical elements 12 as shown by the members 37. Where the interconnecting member 13 has been removed from a member 37, there is less localized mass, and hence less localized stiffness, which affords a more flexible and uniform expansion. The remaining interconnecting members 13 preferably are positioned 180 degrees apart. So at the second end section 31B, adjacent cylindrical elements 12 are connected by only two interconnecting elements 13.

Because of the mass involved with the stent designs of the present invention, the double curved portion 34 is the stiffest structure and the peak portion 36 is the least stiff structure, which accounts for the different stresses which arise during expansion. Also, the least stiff structure, the peak portion 36, is positioned between the double curved portion 34 and the valley portion 30, which are comparatively stiffer structures. To even out the stresses, the peak portion 36 has different curvatures at regions 32 and 33, as seen in FIG. 5. The region 33 has a larger radius than the region 32 and expands more easily. Because the region 32 is adjacent the

stiffer area of the double curved portion 34, both the region 32 and the double curved portion 34 expand more uniformly and more evenly distribute the expansion stresses. Further, the valley portion 30 and the double curved portion 34 have different diameters to even out the expansion forces in relation to the peak portion 36. Due to the novel structure as described, the shortcomings of the prior art, which include out-of-plane twisting of the metal, are avoided. These differing degrees of curvature along the peak portion 36 allow for the more even expansion of a cylindrical element 12 as a whole.

The stent 10 of FIGS. 2-5 has an expansion ratio from the crimped to expanded configuration in the range of about 1.0 to 5.0, while maintaining its structural integrity when expanded. As depicted in FIG. 6, after expansion of the stent 10, portions of the various cylindrical elements 12 may turn outwardly, forming small projections 38 that embed in the vessel wall. More precisely, a tip 39 of the peak portion 36 tilts outwardly a sufficient amount upon expansion of the stent 10 to embed into the vessel wall thus helping to secure the stent 10 when implanted. Upon expansion, the projections 38 create an outer wall surface on the stent 10 that is not smooth. On the other hand, while the projections 38 assist in securing the stent 10 in the vessel wall, the projections are not sharp as to cause trauma or damage to the vessel wall.

The tips 39 projecting outwardly and any twisting of the struts is due primarily to the struts having a high aspect ratio. In one preferred embodiment, the strut width is about 0.0889 mm (0.0035 in.) and a thickness of about 0.0559 mm (0.0022 in.), providing an aspect ratio of 1.6. An aspect ratio of 1.0 will produce less tipping and twisting.

FIG. 7 illustrates an alternative embodiment of a stent according to the present invention. In particular, FIG. 7 is a plan view of a flattened section of a stent 40 with flexible first and second end sections 41A, 41B, respectively, and a relatively rigid center section 42. In this exemplary embodiment, the center section

42 includes preferably four interconnecting members 13 to connect a double curved portion (W) 44 of one cylindrical element 12 to a valley portion (Y) 43 of an adjacent cylindrical element 12. In the exemplary embodiment shown in FIG. 7, the interconnecting members 13 within the center section 42 are spaced 90 degrees apart.

Each cylindrical element 12 is made up of four repeating serpentine wave pattern sections having valley portions (Y) 43, peak portions (U) 46, and double curved portions (W) 44. The valley portions 43 and the peak portions 46 each have a generally single radius of curvature. Each valley portion 43 is connected to a interconnecting member 13 and bridges to a peak portion 46. All of the aforementioned structures preferably lie within the center section 42. At first and second end sections 41A, 41B, every other interconnecting member has been removed to increase flexibility in that region. Therefore, the members 47 are interspersed between the interconnecting members 13 at first end section 31A and second end section 31B. Within the first and second end sections 41A, 41B, interconnecting members 13 preferably are spread 180 degrees apart.

The cylindrical elements 48 found within the first and second end sections 41A, 41B have repeating serpentine wave patterns with valley portions (Y) 43, peak portions (U) 46, and double curve portions (W) 44, but the difference as mentioned above is the omission of interconnecting members 13 to connect the members 47 to adjacent valley portions 43. Therefore, in the exemplary embodiment depicted in FIG. 7, the first end section 41A has three cylindrical elements 48 with three pairs of interconnecting members 13. The same construction applies for the second end section 41B. The center section 42, however, preferably has four cylindrical elements 12, with four sets of four interconnecting members 13.

The interconnecting members 13 may be aligned axially in every other cylindrical element 12, 48, as shown in FIG. 7, or they may be staggered depending on the bending requirements of a particular stent. Indeed, the present invention

controls stent flexibility by using the number of interconnecting members between cylindrical elements of the stents. Generally speaking, the more interconnecting members there are between cylindrical elements of the stent, the less longitudinally flexible is the stent. Thus more interconnecting members reduces flexibility, but increases the coverage of the stent on the vessel wall which helps prevent tissue prolapse between the stent struts.

The exemplary embodiment depicted in FIG. 7 is especially well suited for lesions on bends. In this application, the center section 42 of the stent 40 is placed over the largest plaque burden and the first and second end sections 41A, 41B enable flexing around the bend where there is less plaque to support.

FIG. 8 is a plan view of a flattened section of yet another alternative embodiment of the present invention stent. In this alternative embodiment, a stent 50 has flexible first and second end sections 51A, 51B, respectively, separated by a center section 52. Within each of the first end section 51A, the second end section 51B, and the center section 52 are a plurality of cylindrical elements 53. Each cylindrical element 53 is comprised of a serpentine pattern of opposed U-shaped curves 54. All of the U-shaped curves 54 have an identical radius of curvature, providing a consistent pattern. More precisely, each U-shaped curve 54 has a mouth 55 that is pinched closed by adjacent U-shaped curves 54 to provide a denser strut pattern.

To change the flexibility of the stent 50, the number of interconnecting members 56 is varied along the length of stent 50. For example, in the first end section 51A, there is only one interconnecting member 56 between any two adjacent cylindrical elements 53. Likewise, in the second end sections 51B of the cylindrical elements therein, there only is one interconnecting member 56 linking any two adjacent cylindrical elements 53.

In contrast, the center section 52 preferably has two adjacent cylindrical elements 53 linked by three interconnecting members 56. Both ends of center

section 52 have cylindrical elements 53 linked to adjacent cylindrical elements 53 within the first and second end sections 51A, 51B by use of three interconnecting members 56. To summarize, and with reference to FIG. 8, the stent 50 uses a single interconnecting member 56 to interconnect adjacent pairs of the four cylindrical elements 53 within the first end section 51A; then uses three interconnecting members 56 to interconnect adjacent pairs of the three cylindrical elements 53 within and at opposite ends of the center section 52; and lastly uses one interconnecting member 56 between adjacent pairs of the two cylindrical elements 53 within the second end section 51B.

FIG. 8 illustrates that the number and location of interconnecting members 56 can be changed according to specific design and flexibility requirements. Indeed, the particular number of interconnecting members between cylindrical elements depends on the design configuration and the flexibility desired in each region. For example, an alternative embodiment stent (not shown) could have two interconnecting members between pairs of cylindrical elements at one end section, four interconnecting members between pairs of cylindrical elements in the center section, and one interconnecting member between pairs of cylindrical elements in the second end section. The number of cylindrical elements within an end section or center section, if any, can be changed to customize the stent to a particular application. The number of interconnecting members used between any adjacent pair of cylindrical elements can be varied as necessary. Further, the angular positioning of each interconnecting member and the locations of the interconnecting members relative to each other can be changed depending upon the flexibility requirements. It should be understood that the term "interconnecting member" as used herein can include not only those connecting elements specifically depicted in the drawings, but also welds between adjacent cylindrical elements, or simply an uncut area between cylindrical elements.

The dimensions of any of the foregoing exemplary embodiments can be adjusted to achieve optimal expansion and strength characteristics for a given stent. The number of bends in each cylindrical element, as shown in FIG. 8 for example, also can be varied.

In many of the drawing figures the stent is depicted flat, in a plan view, for ease of illustration. All of the embodiments depicted herein are cylindrically-shaped stents that generally are formed from tubing by laser cutting as will be described.

One important feature of all of the embodiments of the present invention is the capability of the stents to expand from a low-profile diameter to a diameter much greater than heretofore was available, while still maintaining structural integrity in the expanded state and remaining highly flexible. Due to the novel structures, the stents of the present invention each have an overall expansion ratio of about 1.0 up to about 4.0 times the original diameter, or more, using certain compositions of stainless steel. For example, a 316L stainless steel stent of the invention can be radially expanded from a diameter of 1.0 unit up to a diameter of about 4.0 units, which expansion deforms the structural members beyond the elastic limit. The stents still retain structural integrity in the expanded state and will serve to hold open the vessel in which the stents are implanted. Materials other than stainless steel (316L) may afford higher or lower expansion ratios without sacrificing structural integrity.

The present invention contemplates a variety of constructions for the number of interconnecting members and the location of the interconnecting members in the first end section, center section, or second end section of the stent. For example, it is possible to have a stent with a center section having adjacent cylindrical elements connected by n number of interconnecting members, and the adjacent cylindrical elements in at least one of the first or the second end sections are connected by n - k number of interconnecting members, where k is a number from 1 through 5 inclusive and $n > k$.

In an alternative embodiment, n is the number of interconnecting members at the center section, and k is the number of interconnecting members in one of the first or second end sections. In this embodiment, the ratio of n to k includes, for example, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 2:3, 2:5, 3:4, or 3:5.

The stents of the present invention can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled tubular member of, for example, stainless steel tubing, to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. It is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser.

The tubing may be made of suitable biocompatible material such as stainless steel. The stainless steel tube may be alloy-type: 316L SS, Special Chemistry per ASTM F138-92 or ASTM F139-92 grade 2. Special Chemistry of type 316L per ASTM F138-92 or ASTM F139-92 Stainless Steel for Surgical Implants in weight percent.

Carbon (C)	0.03% max.
Manganese (Mn)	2.00% max.
Phosphorous (P)	.025% max.
Sulphur (S)	0.010% max.
Silicon (Si)	0.75% max.
Chromium (Cr)	17.00 - 19.00%
Nickel (Ni)	13.00 - 15.50%
Molybdenum (Mo)	2.00 - 3.00%
Nitrogen (N)	0.10% max.
Copper (Cu)	0.50% max.
Iron (Fe)	Balance

The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically, the stent has an outer diameter on the order of about 1.52 mm (0.06 in.) in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 5.08 mm (0.2 in.) or more. The wall thickness of the tubing is about (0.076 mm) 0.003 in.

Generally, the tubing is put in a rotatable collet fixture of a machine-controlled apparatus for positioning the tubing relative to a laser. According to machine-encoded instructions, the tubing then is rotated and moved longitudinally relative to the laser which also is machine-controlled. The laser selectively removes the material from the tubing by ablation and a pattern is cut into the tube. The tube therefore is cut into the discrete pattern of the finished stent.

The process of cutting a pattern for the stent into the tubing generally is automated except for loading and unloading the length of tubing. For example, a pattern can be cut in tubing using a CNC-opposing collet fixture for axial rotation of the length of tubing, in conjunction with CNC X/Y table to move the length of tubing axially relative to a machine-controlled laser as described. The entire space between collets can be patterned using the CO_2, Nd, or YAG laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coding.

Cutting a fine structure (0.0863 mm (0.0034 in.) web width) requires minimal heat input and the ability to manipulate the tube with precision. It also is necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the entire system must be configured very carefully. The tubes are made of stainless steel with an outside diameter of 1.52 mm (0.060 in.) to 2.54 mm (0.10 in.) and a wall thickness of 0.051 mm (0.002 in.) to 0.203 mm (0.008 in). These tubes are fixtured under a laser and positioned utilizing CNC to generate a very intricate and precise

pattern. Due to the thin wall and the small geometry of the stent pattern 0.889 mm (0.0035 in. typical strut width), it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

In order to minimize the heat input into the stent structure, which prevents thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, and thereby produce a smooth debris-free cut, a Q-switched Nd/YAG laser, (a laser which typically is available from Quantonix of Hauppauge, New York), that is frequency-doubled to produce a green beam at 532 nanometers is utilized. Q-switching produces very short pulses (<100 nS) of high peak powers (kilowatts), low energy per pulse (≤3 mJ), at high pulse rates (up to 40 kHz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is two times smaller, therefore increasing the power density by a factor of four times. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless steel tubes in very fine geometries without damaging the narrow struts that make up the stent structure. Hence, the system of the present invention makes it possible to adjust the laser parameters to cut narrow kerf width which will minimize the heat input into the material.

The positioning of the tubular structure requires the use of precision CNC equipment such as that manufactured and sold by the Anorad Corporation. In addition, a unique rotary mechanism has been provided that allows the computer program to be written as if the pattern were being cut from a flat sheet. This allows both circular and linear interpolation to be utilized in programming.

The optical system which expands the original laser beam, delivers the beam through a viewing head and focuses the beam onto the surface of the tube, incorporates a coaxial gas jet and nozzle that helps to remove debris from the kerf and cools the region where the beam interacts with the material as the beam cuts and vaporizes the metal. It also is necessary to block the beam as it cuts through the top

surface of the tube and to prevent the beam, along with the molten metal and debris from the cut, from impinging on the opposite surface of the tube.

In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer, typically in the form of a quarter wave plate, to eliminate polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle 0.457 mm (0.018 in.). Inner diameter (I.D.) is centered around the focused beam with approximately 0.254 mm (0.010 in.). between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 1.36 bars (20 psi) and is directed at the tube with the focused laser beam exiting the tip of the nozzle 0.457 mm (0.018 in.) diameter. The oxygen reacts with the metal to assist in the cutting process very similar to oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision.

In order to prevent burning by the beam and/or molten slag on the far wall of the tube I.D., a stainless steel mandrel approximately 0.863 mm (0.034 in.) diameter is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This acts as a beam/debris barrier protecting the I.D. of the far wall.

Alternatively, this preventive action may be accomplished by inserting a second tube inside the stent tube which has an opening to trap the excess energy in the beam that is transmitted through the kerf along with the collected debris that is ejected from the laser cut kerf. A vacuum or positive pressure can be placed in this shielding tube to remove the collected debris.

Another technique that could be used to remove the debris from the kerf and to cool the surrounding material would be reliance upon the inner beam blocking

tube as an internal gas jet. By sealing one end of the tube and making a small hole in the side and placing it directly under the focused laser beam, gas pressure could be applied, creating a small jet that would force the debris out of the laser cut kerf from the inside out. This would eliminate any debris from forming or collecting on the inside of the stent structure. It would place all the debris on the outside. With the use of special protective coatings, the resultant debris easily could be removed.

In most cases, the gas utilized in the jets may be reactive or non-reactive (inert). In the case of reactive gas, oxygen or compressed air is used. Oxygen is used in this application because it offers more control of the material removed and reduces the thermal effects of the material itself. Inert gases such as argon, helium, or nitrogen can be used to eliminate any oxidation of the cut material. The result is a cut edge with no oxidation, but there usually is a tail of molten material that collects along the exit side of the gas jet that must be mechanically or chemically removed after the cutting operation.

The cutting process using oxygen with the finely focused green beam results in a very narrow kerf (approximately 0.0127 mm (0.0005 in.)) with the molten slag re-solidifying along the cut. This traps the cut-out scrap of the pattern requiring further processing. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is necessary to soak the cut tube in a solution of HCl for approximately eight minutes at a temperature of approximately 55°C. Before it is soaked, the tube is placed in a bath of alcohol/water solution and ultrasonically cleaned for approximately one minute to remove the loose debris left from the cutting operation. After soaking, the tube is cleaned ultrasonically in the heated HCl for one to four minutes depending upon the wall thickness. To prevent cracking/breaking of the struts attached to the material left at the two ends of the stent pattern due to harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the

cleaning/scrap removal process. At completion of this process, the stent structures are rinsed in water. They are now ready for electropolishing.

The stents preferably are electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO Co., Inc. in Chicago, Illinois, which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 43.3-56.1 °C (110-133 °F) and the current density is about 0.062 to about 0.233 amps per cm (about 0.4 to about 1.5 amps per in^2). Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

Direct laser cutting produces edges which are essentially perpendicular to the axis of the laser cutting beam, in contrast with chemical etching and the like which produce pattern edges which are angled. Hence, the laser cutting process of the present invention essentially provides stent cross-sections, from cut-to-cut, which are square or rectangular, rather than trapezoidal. The resulting stent structure provides superior performance.

The stent tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, super-elastic (nickel-titanium (NiTi)) alloys and even high strength thermoplastic polymers. The stent diameters are very small, so the tubing from which it is made must necessarily also have a small diameter. For PCTA applications, typically the stent has an outer diameter on the order of about 1.65 mm (0.065 in.) in the unexpanded condition, the same outer diameter of the hypotubing from which it is made, and can be expanded to an outer diameter of 5.08 mm (0.2 in.) or more. The wall thickness of the tubing is about 0.076 mm (0.003 in.). For stents implanted in other body lumens, such as PTA applications, the dimensions of the tubing are correspondingly larger. While it is preferred that the stents be made from laser cut tubing, those skilled in the art will realize that the

stent can be laser cut from a flat sheet and then rolled up in a cylindrical configuration with the longitudinal edges welded to form a cylindrical member.

In the instance when the stents are made from plastic, the implanted stent may have to be heated within the arterial site where the stents are expanded to facilitate the expansion of the stent. Once expanded, it then would be cooled to retain its expanded state. The stent may be conveniently heated by heating the fluid within the balloon or the balloon itself directly by a known method.

The stents also may be made of materials such as super-elastic (sometimes called pseudo-elastic) NiTi alloys. In this case, the stent would be formed fully sized but deformed (e.g., compressed) to a smaller diameter onto the balloon of the delivery catheter to facilitate intraluminal delivery to a desired intraluminal site. The stress induced by the deformation transforms the stent from an austenite phase to a martensite phase, and when the force is released when the stent reaches the desired intraluminal location, the stent is allowed to expand due to the transformation back to the more stable austenite phase. Further details of how NiTi super-elastic alloys operate can be found in U.S. Patent Nos. 4,665,906 (Jervis) and 5,067,957 (Jervis).

While the invention has been illustrated and described herein in terms of its use as intravascular stents, it will be apparent to those skilled in the art that the stents can be used in other instances in all vessels in the body. Because the stents of the present invention have the novel feature of expanding to very large diameters while retaining their structural integrity, the stents are particularly well suited for implantation in almost any vessel where such devices are used. This feature, coupled with limited longitudinal contraction of the stent when the devices are radially expanded, provide a highly desirable support member for all vessels in the body. Other modifications and improvements may be made without departing from the scope of the invention.

WHAT IS CLAIMED IS:

1. A longitudinally flexible stent for implanting in a body lumen and expandable from a contracted condition to an expanded condition, comprising:

a plurality of adjacent cylindrical elements each having a circumference extending around a longitudinal stent axis, the cylindrical elements being arranged in cylindrical alignment along the longitudinal stent axis to form a generally tubular member;

the generally tubular member having a first end section, a second end section, and a center section therebetween;

wherein the adjacent cylindrical elements in the center section are connected by n number of interconnecting members and the adjacent cylindrical elements in at least one of the first and the second end sections are connected by n-k number of interconnecting members, so that the first and second sections are relatively more flexible than the center section;

wherein k is a number selected from the group consisting of 1, 2, 3, 4, or 5; and

wherein $n > k$.

2. The stent of claim 1, wherein both the first and the second end sections include adjacent cylindrical elements that are connected by n-k number of interconnecting members.

3. The stent of claim 1, wherein the stent is laser cut from tubing.

4. The stent of claim 1, wherein at least one of the first and second end sections has n interconnecting members.

5. The stent of claim 1, wherein each cylindrical element is formed in a generally serpentine wave pattern transverse to the longitudinal axis, the serpentine wave pattern having a plurality of alternating peak portions, valley portions and double curved portions.

6. The stent of claim 5, wherein the n and the n-k interconnecting members connect the valley of one cylindrical element with a double curved portion of an adjacent cylindrical element.

7. The stent of claim 1, wherein the cylindrical members are configured for expanding from a first smaller diameter to a range of enlarged diameters without appreciable change in the length of the stent.

8. The stent of claim 5, wherein the peak portions have irregular radii of curvature so that upon expansion, the peak portions uniformly and evenly expand.

9. The stent of claim 1, wherein the stent is formed from a flat piece of material.

10. The stent of claim 1, wherein the stent is formed of a biocompatible material selected from the group consisting of stainless steel, tungsten, tantalum, super-elastic nickel-titanium alloys, or thermoplastic polymers.

11. The stent of claim 1, wherein the stent has a radial expansion ratio of about 1.0 in the contracted condition up to about 4.0 in the expanded condition.

12. The stent of claim 1, wherein the stent is formed from a single piece of tubing.

13. A longitudinally flexible stent for implanting in a body lumen and expandable from a contracted condition to an expanded condition, comprising:

a plurality of adjacent cylindrical elements each having a circumference extending around a longitudinal stent axis and each element being substantially independently expandable in the radial direction, each element being arranged in alignment along the longitudinal stent axis;

wherein the plurality of adjacent cylindrical elements define a first end section, a second end section, and a center section therebetween;

the cylindrical elements formed in a generally serpentine wave pattern transverse to the longitudinal axis and containing alternating valley portions, peak portions and double-curved portions, each cylindrical element being arranged so that the peaks of adjacent cylindrical elements are out of phase;

a plurality of interconnecting members extending between the adjacent cylindrical elements and connecting valley portions and double-curved portions of adjacent cylindrical elements to one another;

wherein the stent includes a fewer number of the interconnecting members being positioned at least in one of the first and second end sections, and a greater number of the interconnecting members being positioned in the center section.

14. The stent of claim 13, wherein the shape and size along adjacent peak portions and valley portions of the serpentine pattern are different.

15. The stent of claim 13, wherein the cylindrical elements cooperate to define a generally smooth cylindrical surface and wherein the peak portions form projecting edges which project outwardly from the cylindrical surface upon expansion.

16. The stent of claim 13, wherein said stent is formed of a biocompatible material selected from the group consisting of stainless steel, tungsten, tantalum, super-elastic nickel-titanium alloys, or thermoplastic polymers.

17. The stent of claim 13, wherein said stent has a radial expansion ratio of about 1.0 in the contracted condition up to about 4.0 or more in the expanded condition.

18. The stent of claim 13, wherein the first and second end sections contain an unequal number of interconnecting members.

19. A longitudinally flexible stent for implanting a body lumen and expandable from a contracted condition to an expanded condition, comprising:

a plurality of adjacent cylindrical elements, each having a circumference extending around a longitudinal stent axis and each element being expandable in the radial direction, the elements being arranged in alignment along the longitudinal stent axis;

a cylindrical element formed in a generally serpentine wave pattern and containing a plurality of alternating peak portions, valley portions and double-curved portions;

wherein adjacent cylindrical elements are joined by interconnecting members to form a first end section, a second end section, and a center section therebetween;

wherein the stent includes n number of interconnecting members at the center section and k number of interconnecting members in at least one of the first and second end sections;

wherein the ratio of n:k is selected from the group consisting of 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 2:3, 2:5, 3:4, or 3:5.

20. The stent of claim 19, wherein the stent includes k number of interconnecting members in the first and second end sections.

21. The stent of claim 20, wherein each of the double-curved portions in the first end section includes an interconnecting member.

22. The stent of claim 21, wherein each double-curved portion in the second end section includes an interconnecting member.

23. The stent of claim 20, wherein every other double-curved portion in at least one of the first and second end sections includes an interconnecting member.

24. The stent of claim 20, wherein at least one of the first and second end sections and the center section have an identical number of interconnecting members.

FIG. 1

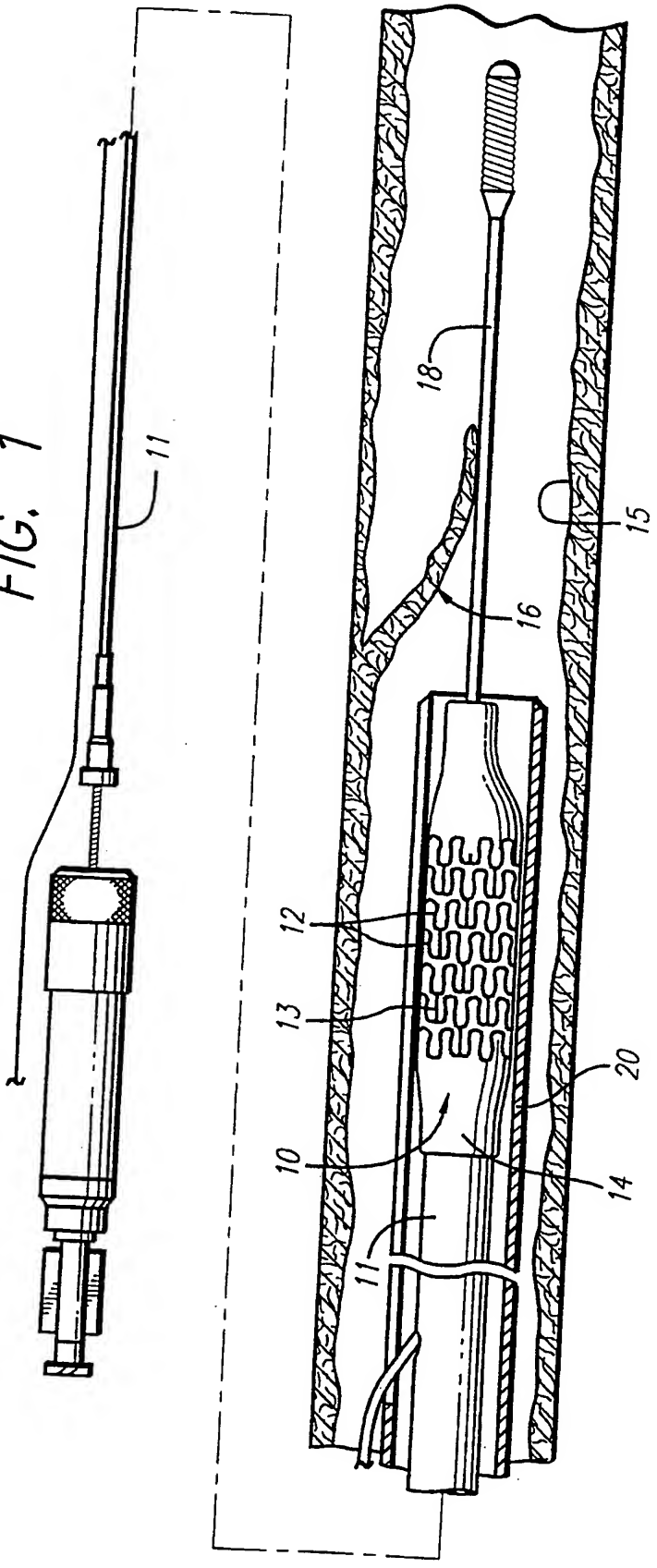


FIG. 3

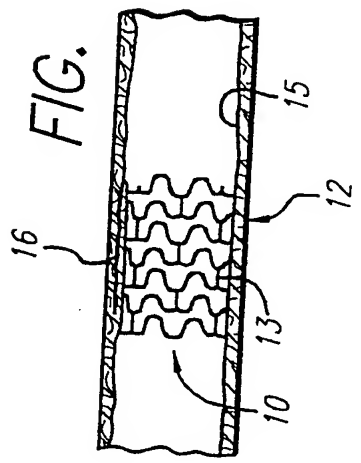
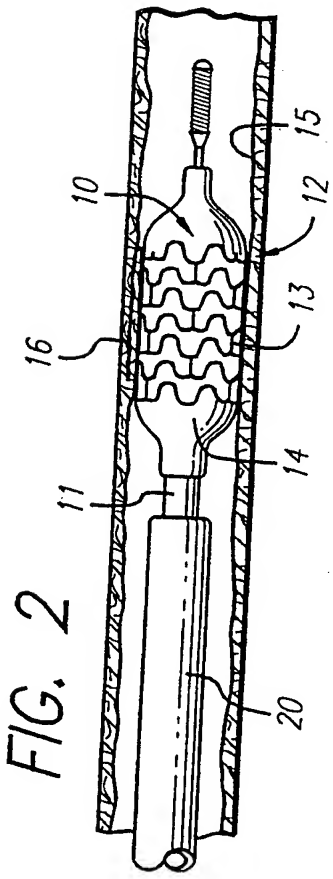


FIG. 2



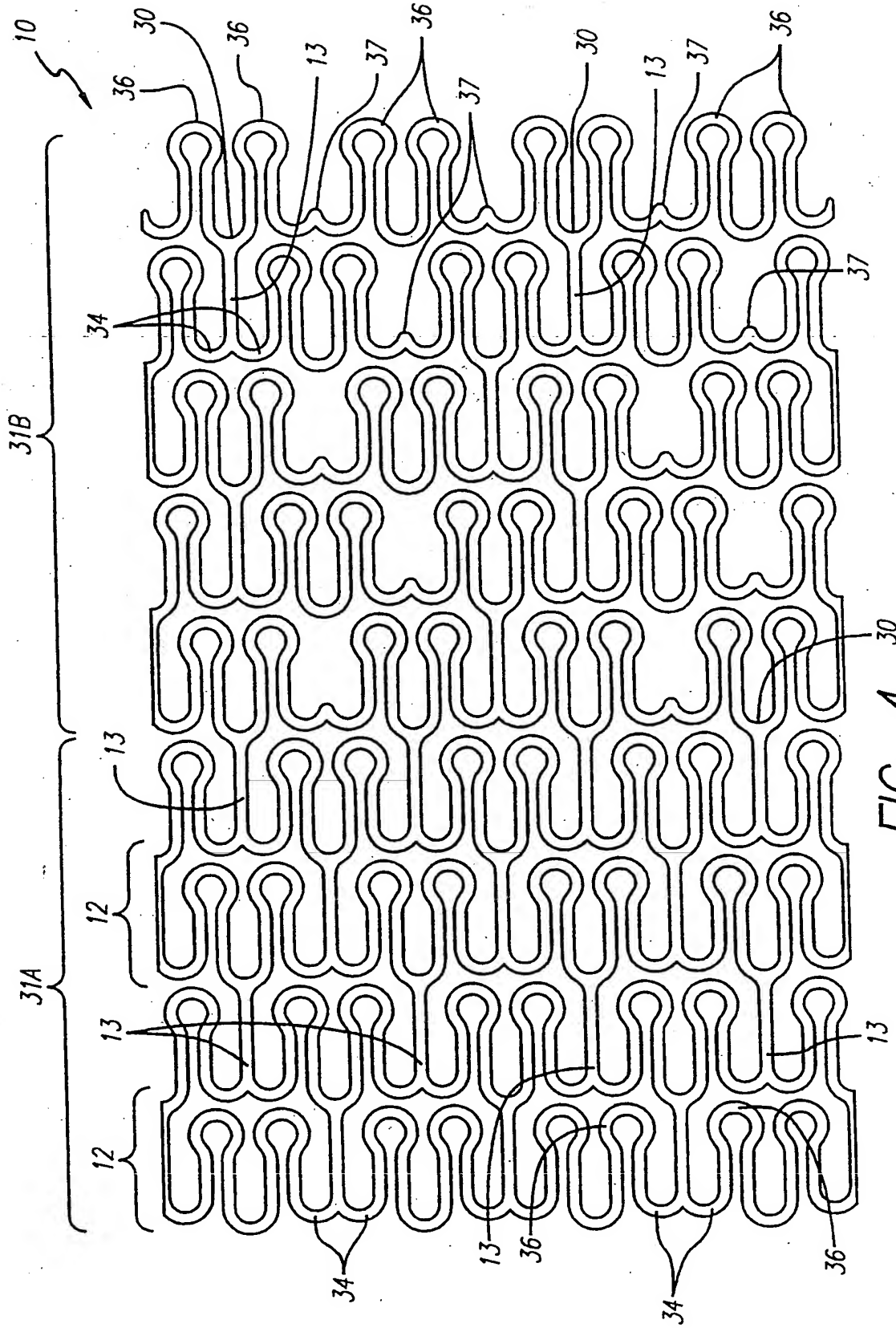

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FIG. 4

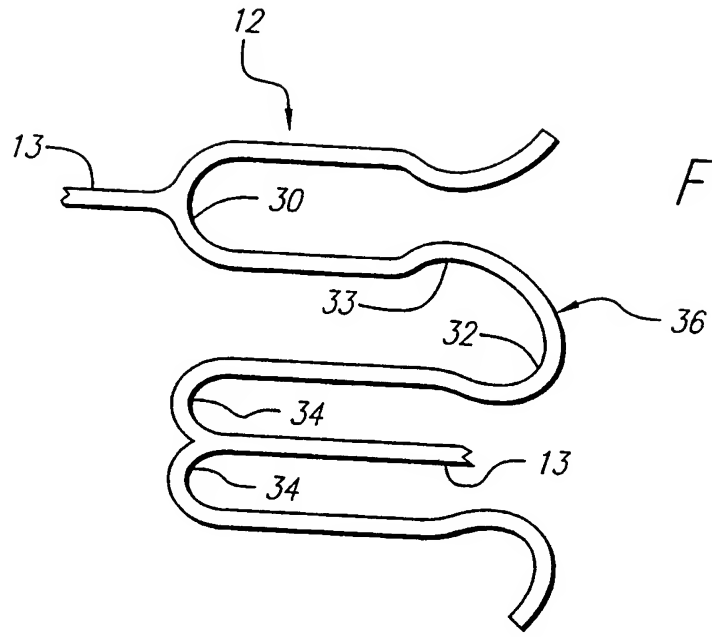

FIG. 5

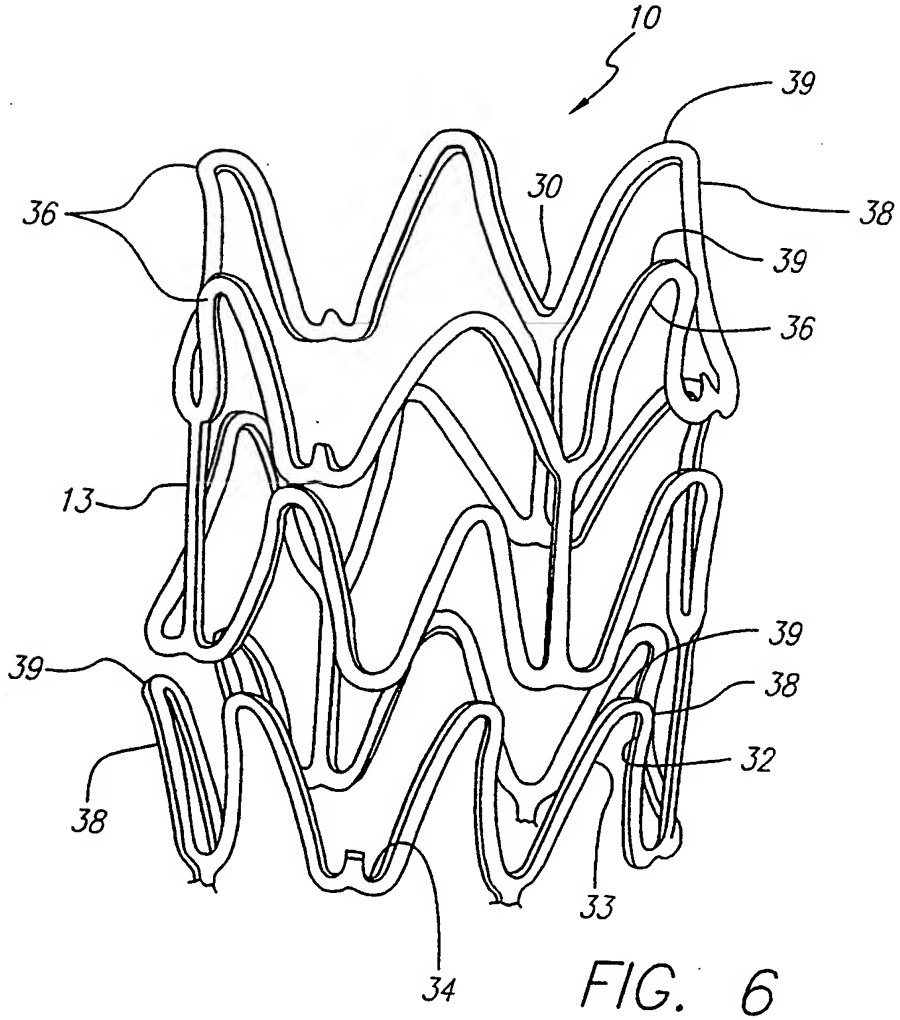

FIG. 6

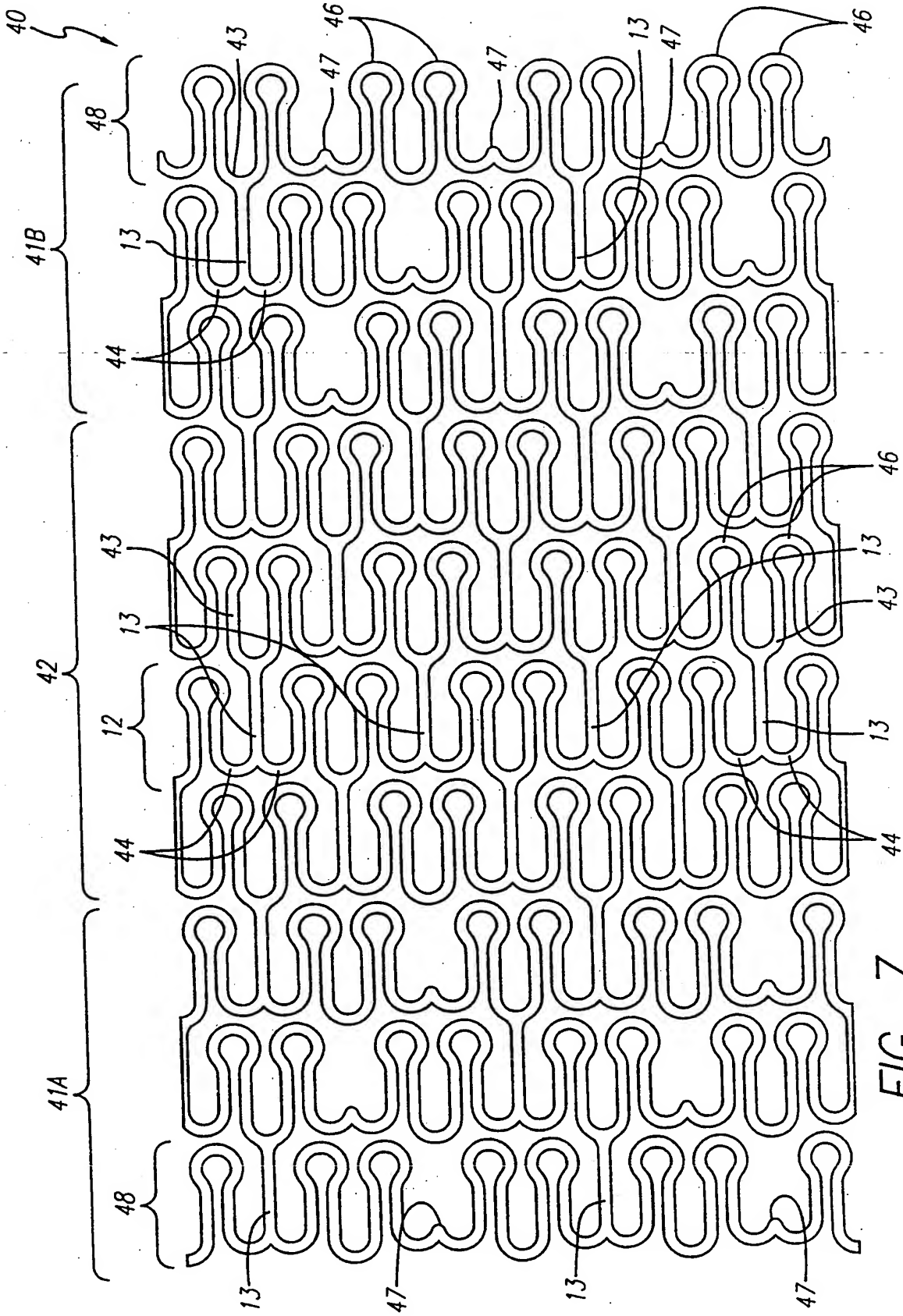
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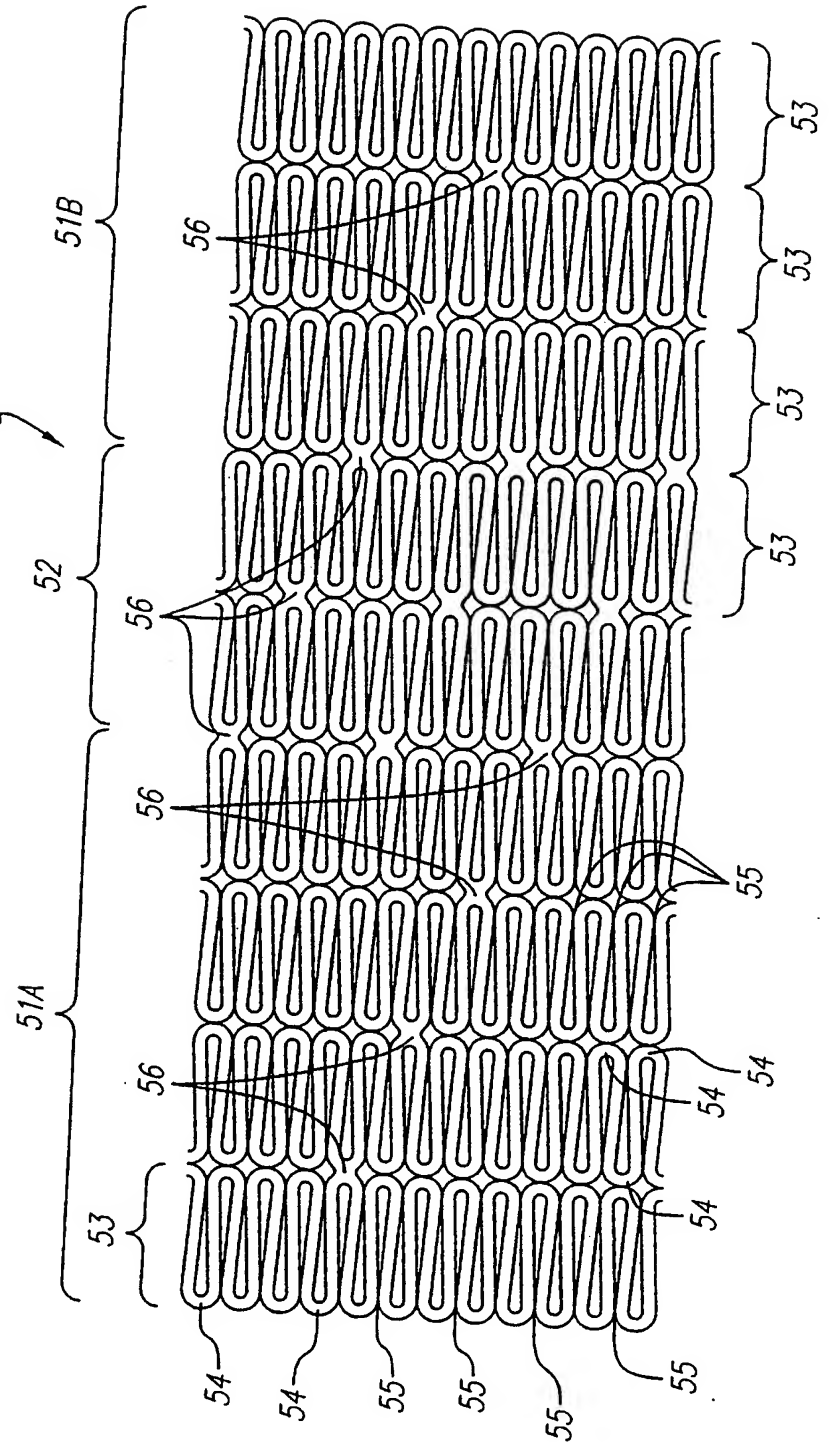
FIG. 7

FIG. 8



INTERNATIONAL SEARCH REPORT

Inte. onal Application No
PCT/US 00/04323

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 297 08 879 U (JOMED IMPLANTATE GMBH) 31 July 1997 (1997-07-31) figures 2,3 claims 1-8	1,3-5, 7-19
A	page 6, line 1 -page 7, line 12	6,20-24
X,P	US 5 938 697 A (KILLION DOUGLAS P ET AL) 17 August 1999 (1999-08-17) figures 4,5 column 4, line 58 -column 5, line 7 column 5, line 45 - line 55 claims 1-12	1-4,7,9, 10,12
A		5,6, 13-24

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 June 2000	28/06/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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INTERNATIONAL SEARCH REPORT

Inte ional Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	WO 97 25937 A (JANG G DAVID) 24 July 1997 (1997-07-24) figure ALL page 9, line 34 -page 11, line 31 page 12, line 9 -page 14, line 14 claims 1-10	1,13,19
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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
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